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| 10/083,825 | 02/27/2002 | Roger K. Khouri | STK-066C2 (7557/36) | 8501 |

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | | |
|-----------------|------------|----------------|---------------|
| Application No. | 10/083828 | Applicant(s) | Khouri, et al |
| Examiner | <i>dcf</i> | Group Art Unit | 1657 |
| | | | |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 2/27/02

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

Claim(s) 1-33 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-33 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). *2/27/02* *5/3/02* Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

Office Action Summary

Claims examined on the merits are 1-33 which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

5 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10 Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 In line 5 of claim 1 and where recited in other claims "residues" is uncertain as to meaning and scope. Material that is and is not a residue is uncertain. The relationship of the residues to the matrix is unclear. Do the residues form the matrix or are they material in addition to the matrix?

20 Claim 1 is unclear as to the relationship of the osteogenic protein to the matrix and to the residues. Is the protein contained by the matrix or is the protein combined with the matrix in some other way? Where is the location of the residues with respect to the protein?

25 Claims 3-6, 8, 14-16, 20 and 22 are unclear as to whether the tissue or residues or material required are in addition to the matrix or form the matrix. If the matrix contains the tissue, residues or material, it should be made clear as to where the tissue, residues or

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material is contained within the matrix structure with respect to the osteogenic protein.

Claim 9 is unclear as to the meaning of "device further defines a devitalized intact skeletal joint structure". How can the device 5 further define a joint structure?

In claims 10, 11, 18, 20, 24 and 26 "residues" is unclear for reasons set forth above.

In claim 29, it is unclear as to the meaning and scope of "matrix derived from allogenic or xenogenic articular cartilage". The form of 10 the matrix when "derived" is uncertain.

Claims 30 and 31 are unclear as to where the structure of the matrix comprises a moldable solid or a flexible sheet. Are the solid and sheet in addition to the matrix or is the matrix in the form of a moldable solid or sheet? Also, a solid being moldable is relative and 15 subjective.

Claim 32 is unclear as to whether the materials required or in addition to the matrix or form the matrix.

In claims 17 and 33, "or functional equivalents thereof" is uncertain as to meaning and scope. Being functionally equivalent is 20 relative and subjective.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

25 A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 3, 6, 18-20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuberanampath et al (5,171,574) (AQ) or (4,975,526) (AE).

The claims are drawn to a device for implanting to form a body part containing plural distinct tissues. The device is formed of a biodegradable matrix comprising residues of the plural distinct tissues and an osteogenic protein. Also claimed is a method of using the device to form an autologous replacement body part.

Kuberanampath et al discloses a demineralized extracted bone matrix containing osteogenic protein for implanting to make new bone. Bone contains plural distinct tissues.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuberampath et al (5,171,574) or (4,975,526) in view of Vacanti et al (5,041,138) (AH) and Hunziker (5,270,300) (AV).

The invention and Kuberampath et al are described above.

5 Dependent claims and other claims require the plural distinct tissues to be non-mineralized such as articular cartilage.

Vacanti et al disclose implanting a synthetic polymer matrix containing chondrocytes to form new cartilage.

10 Hunziker discloses repairing defects in bone or cartilage by implanting a matrix containing an osteogenic factor. Various matrix materials may be used (col 7, lines 37-61) and include fibrinogen and collagen matrixes.

15 It would have been obvious to apply the extraction procedure of Kuberampath et al to cartilaginous tissues other than bone tissue such as joint cartilaginous tissue containing plural distinct tissues as suggested by Vacanti et al and Hunziker producing new cartilage by implanting different types of matrix materials, which include collagen that is the primary constituent of cartilage. Selecting specific tissues to replace would have been a matter of obvious choice 20 depending on tissue function needed repairing.

Double Patenting

25 The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 30 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

5 Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10 Claims 1-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,110,482 or claims 1-9 of U.S. Patent No. 5,906,827 or claims 1-19 of U.S. Patent No. 6,027,743. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed device would have been 15 obvious from the same type of device claimed by the claims of the patents.

Any inquiry concerning this communication or earlier 20 communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this 25 application is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is 703-308-0196.

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David M. Naff
Primary Examiner
Art Unit 1651

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15 DMN
9/26/03